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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,773	08/10/2001	Russell O. Potts	0240.02	6897

7590 09/22/2003

CYGNUS, INC.  
Intellectual Property Dept.  
400 Penobscot Drive  
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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/927,773	POTTS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Marjorie A. Moran	1631	

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Priority***

The wording in the first paragraph of the specification which recites "priority to" a Provisional application under 35 USC 119(e) is improper. The proper phrasing which should be recited before a US Provisional Application is --claims benefit of-- or a phrase similar thereto. The phrase "for which priority is claimed" should be used only when priority is claimed to a US application under 35 USC 120. Appropriate correction is required.

***Information Disclosure Statement***

The information disclosure statement filed 6/16/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but not all of the information referred to therein has been considered. Reference AC-4 by DAVIES et al. was not received with the IDS and has not been considered. All other references have been considered. The examiner's signature on the IDS indicates that only the initialed references have been considered.

The references listed on the IDS filed 3/4/02 are duplicative of references cited on the IDS filed 1/23/02. In order to prevent duplication, the references have been crossed out on the IDS filed 3/4/02, and have been initialed on the IDS filed 1/23/02, in order to indicate consideration thereof.

The IDS's filed 1/23/02 and 3/25/02 have been considered in full.

***Claim Objections***

Claim 10 is objected to because of the following informalities: the term "reservoir" in line 2 should be --reservoirs---. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 recite the limitation "the sampling system", each in line 1. There is insufficient antecedent basis for this limitation in the claims, therefore the claims are indefinite. This rejection may be overcome by inserting --transdermal-- before "system" in each claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being obvious over KURNIK IDS ref: WO 99/58973) in view of TAMADA et al. (IDS ref : JAMA (11/17/1999) vol. 282 (19), pp. 1839-1844).

The claims recite a method for predicting a hypoglycemic event in a subject, and a system and microprocessor comprising a program for running the method, wherein a threshold glucose value corresponding to a hypoglycemic event is determined, a threshold parameter value, specifically for skin conductance or temperature, corresponding to a hypoglycemic event is determined, multiple steps of obtaining a

series of glucose measurement values at selected time intervals by extracting glucose transdermally, obtaining a raw signal for the extracted glucose, and correlating the raw signal to an amount or concentration of glucose are performed, then a glucose value at a further time interval is predicted. The predicted value is compared to the threshold glucose value, wherein a predicted value lower than the threshold value is designated as hypoglycemic. Simultaneously or sequentially with the above steps, a parameter value or trend of parameter values are obtained and compared to the threshold parameter value to determine if the measured or trend parameter value(s) indicate a hypoglycemic event. If both comparisons indicate a hypoglycemic event, then a hypoglycemic event is predicted for the subject. Claims 2, 20, and 29 limit the time intervals to be evenly spaced. Claims 3, 21, and 30 limit the series of measurement values to comprise at least three discrete values. Claims 4, 22, and 31 limit the further time interval to occur after the series of measurement values. Claims 5, 23, and 32 limit the method/program to one wherein both skin conductance and temperature readings are used to predict a hypoglycemic event. Claims 6-7, 24-25, and 33-34 limit the prediction based on the series of measurement values to be calculated by a specific equation. Claims 8 and 18 limit the sampling system to comprise a sweat probe. Claims 9 and 19 limit the sampling system to comprise a temperature probe. Claim 10 limits sample extraction to be into a collection reservoir wherein glucose is obtained. Claim 11 limits the collection reservoir to be in contact with skin or a mucosal surface and limits extraction to be via an iontophoretic current. Claim 12 limits the collection reservoir to comprise an enzyme which reacts with extracted glucose to produce an

electrochemically detectable signal. Claim 13 limits the enzyme to glucose oxidase. Claims 16 and 27 limit the system and microprocessor to comprise a sensing mechanism with an electrochemical sensing element. Claims 14, 17 and 28 limit the measurement/sensing element to comprise a near-IR spectrometer.

KURNIK teaches a method for predicting analyte values, and teaches a system and microprocessor comprising a program for running his method wherein a raw value for the analyte is obtained, correlated to the analyte concentration, a series of evenly spaced measurement values are obtained and used to predict the analyte value at a time interval one measurement after the series of measurement values (p. 2, line 15-p. 3, line 1). KURNIK teaches that his sensing apparatus may be transdermal, placed in contact with skin or a mucosal surface, may use iontophoresis, and may comprise an electrochemical sensing element (p. 3, lines 19-32). KURNIK teaches a TSES function identical to that recited in the claims for predicting glucose values (p. 4, line 20-p. 6, line 24). KURNIK teaches that his sensing mechanism may comprise a near-IR spectrometer (p. 6, lines 8-15). See also page 7, lines 11-32. KURNIK teaches that a suitable enzyme for use in his system and method is glucose oxidase (p. 22, lines 19-30). KURNIK further teaches that both perspiration (sweat) and skin temperature may be monitored before, during, and after glucose measurement, and teaches that perspiration may contain glucose (p. 43, lines 7-22). KURNIK teaches that an additional measurement for prediction is taken after three or more discrete measurements are obtained for a target analyte (p. 44, lines 1-17). KURNIK teaches that his predicted glucose values allows for prediction of hypoglycemic events prior to reaching a "critical

level” (p. 51, line 15-p. 52, line 2). KURNIK does not specifically teach comparison of his predicted glucose levels to a threshold glucose value, nor does KURNIK teach comparison of his measured parameter values (sweat and skin temperature) to a threshold parameter value.

TAMADA teaches a system and method for monitoring glucose levels in a subject wherein an alarm is sounded if glucose values fall below a user-selected threshold (alert level, p. 1839) and/or if skin conductance and temperature values exceed set thresholds (p. 1841). TAMADA specifically teaches that both sweat and temperature fluctuations are associated with glucose measurements, and teaches that both skin conductance measurements and glucose measurements are compared to thresholds and used to predict/indicate hypoglycemia (p. 1841).

It would have been obvious to one of ordinary skill in the art to have compared both the glucose prediction and measured parameter values (sweat and skin temperature) of KURNIK to threshold values, as taught by TAMADA, where the motivation would have been to reduce the risk of hypoglycemia and make therapy for diabetes safer and more acceptable to patients, as taught by TAMADA (p. 1840). It would further have been obvious to have used both glucose concentration prediction and measurement of sweat/temperature, as taught by TAMADA, to predict a hypoglycemic event in the method and products of KURNIK where the motivation would have been to include parameters known to be associated with hypoglycemia, as taught by both KURNIK and TAMADA.



**Conclusion**

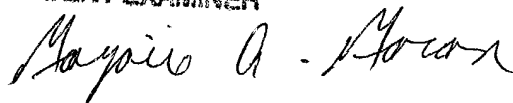
Claims 1-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER

A handwritten signature in black ink, appearing to read "Marjorie A. Moran", is written over the printed name and title.

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